

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellant(s): Perez-Camargo, et al.
Appl. No.: 10/509,951
Conf. No.: 3093
Filed: October 4, 2004
Title: METHOD OF IMPROVING ABSORPTION OF VITAMIN E BY A PET
ANIMAL
Art Unit: 1612
Examiner: Snigdah Maewall
Docket No.: 3714652-00509

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF

Sir:

I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated November 1, 2010 pursuant to 37 C.F.R. § 41.41(a). Appellants respectfully submit that the Examiner's Answer has failed to remedy the deficiencies with respect to the Final Office Action dated December 8, 2009 and the Advisory Action dated May 13, 2010, as noted in Appellants' Appeal Brief filed on July 28, 2010, for at least the reasons set forth below. Accordingly, Appellants respectfully request that the rejections of pending Claims 35, 45, 48-52 and 57-64 be reversed.

II. THE REJECTION OF CLAIMS 35, 45, 48-52 AND 57-64 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS AND, EVEN IF THE EXAMINER ESTABLISHED A *PRIMA FACIE* CASE OF OBVIOUSNESS, APPELLANTS HAVE REBUTTED THE *PRIMA FACIE* CASE OF OBVIOUSNESS

Appellants respectfully request that the Board reverse the rejections of Claims 35, 37, 39-41, 43, 45, 48-52 and 54-68 under 35 U.S.C. §103(a) because the Examiner has still failed to establish a *prima facie* case of obviousness with respect to the cited references. Appellants respectfully submit that the cited references fail to disclose or suggest each and every element of the present claims and that, even if the Examiner establishes a *prima facie* case of obviousness, Appellants have rebutted the *prima facie* case of obviousness.

1. The Examiner Has Failed to Establish a *Prima Facie* Case of Obviousness

In the Examiner's Answer, the Examiner does not dispute the fact that none of the cited references disclose or suggest the presently claimed amounts of taurine. However, the Examiner maintains that the combination of *Couzy*, *Pearson*, *Simpson*, *Watson*, *DeMichele*, and *Margolin* renders the claimed subject matter obvious. See, Examiner's Answer, pages 15-19. The Examiner states that since the specification teaches vitamins as a liver function promoter, and since *Couzy* teaches vitamins in the presently claimed ranges, one of ordinary skill would have envisaged utilizing taurine with an expectation to obtain similar results. See, Examiner's Answer, page 16. Appellants respectfully disagree.

Appellants initially note that although *Couzy* mentions the use of taurine, *Couzy* never teaches a level or range for taurine. *Watson* and *DeMichele* fail to teach the use of or even mention any taurine. The Examiner relies on *DeMichele* for a disclosure of fish oil and *Simpson* and *Margolin* to arguably teach lipid assimilation. Nevertheless, taurine is not disclosed in any of the cited references as a liver function promoter. Instead, the Examiner appears to be using the specification as a guide map for finding the present claims obvious. Indeed, the Examiner even states that "*Couzy* et al. as discussed in the rejection does teach vitamins (described as liver function promoter[s] in [the] instant specification as discussed above in the rejection)." See, Examiner's Answer, page 16, lines 10-12. From this, the Examiner concludes that since

vitamins and taurine are disclosed in the present specification as liver function promoters, and even though none of the cited references discloses taurine as a liver function promoter, the skilled artisan would have known to use taurine as a liver function promoter. As such, the Examiner appears to be using information from the specification to build a case of obviousness against the present claims. This type of hindsight recreation of the pending claims has been found time and again to be improper by the Federal Circuit.

Further, Appellants respectfully submit that even if the prior art discloses vitamins in the amounts presently claimed, there exists no reason why the skilled artisan would have assumed that an amino acid (e.g., taurine) would function similar to the vitamins disclosed by *Couzy* for the purposes of promoting liver function. Additionally, Appellants also submit that it does not matter if *Pearson* teaches that bile salts are synthesized in the liver from cholesterol conjugated with taurine and within the gastrointestinal lumen these bile salts play an essential role in lipid absorption and fat transport. Instead, it is well known that taurine is a major constituent of bile and can be found in the lower intestine. This does not speak at all, however, to additional levels of taurine that may be ingested to promote function of the liver.

As such, Appellants respectfully submit that the Examiner continues to pick and choose selected portions of the cited references to arrive at the present claims. In fact, what the Patent Office has done here is to apply hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Appellants respectfully submit that if it is proper for the Patent Office to combine any number of references to arrive at the present claims simply because each reference suggests an element of the present claims, then every invention would effectively be rendered obvious. Instead, the skilled artisan must have a reason to combine the cited references to arrive at the present claims. Appellants respectfully submit that such a reason is not present in the instant case.

2. Appellants Have Rebutted Any *Prima Facie* Case of Obviousness

Further, Appellants respectfully submit that, even if it were true that such a modification were obvious to the skilled artisan at the time of the invention and in view of the prior art, which Appellants submit is not the case, it is well established that such a finding may be rebutted by Appellants. For example, the Manual of Patent Examining Procedures (“MPEP”) states that “[i]f

a *prima facie* case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the *prima facie* case.” See, MPEP Section 2145 (quoting *In re Dillon*, 919 F.2d 688, 692, (Fed. Cir. 1990)). Initially, Appellants submit that the Examiner has failed to even establish a *prima facie* case of obviousness because the cited references fail to disclose or suggest each and every element of the present claims. However, assuming that the Examiner has established a *prima facie* case of obviousness, Appellants have rebutted same.

For example, the MPEP also states that “[r]ebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties.” See, *In re Dillon*, 919 F.2d 688, 692, at 692-93, (Fed. Cir. 1990). “A showing of unexpected results must be based on evidence, not argument or speculation.” See, *In re Mayne*, 104 F.3d 1339, 1343-44, (Fed. Cir. 1997). Appellants respectfully disagree with the Examiner’s repeated assertions that the previously submitted *Declaration* contains insufficient evidence of surprising results.

For example, the Examiner states that “[t]here is no fat digestion data presented so that comparison of cats with low or high absorption of fat with respect to consuming diet[s] with only citric acid, or taurine or fish oil can be compared with cats that consumed diet[s] with only citric acid, or taurine or fish oil can be compared with cats that consumed diet[s] with [a] combination of the three ingredients such as citric acid, taurine and fish oil.” See, Examiner’s Answer, page 18, lines 11-15. In contrast, Appellants submit that the *Declaration* expressly discloses tests performed with a random group of cats and compares cats that ate a diet of control diet A+citric acid, with cats that ate a diet of control diet A+taurine, and cats that ate a diet of control diet A+fish oil, and cats that ate a diet of the combination of citric acid, taurine and fish oil in diet C.

As supported by the *Declaration*, Diet A + citric acid, Diet A + taurine, and Diet A + fish oil showed an increase in fat digestibility of 6.6%, 6.1% and 5.5%, respectively, when compared to the control diets. However, surprisingly, the combination of the three promoters showed a much more pronounced and synergistic effect on fat digestibility. The combination (Diet C) showed an increase in fat digestibility of 17.5%. In old cats with reduced fat digestibility (<80%), the presence of a single pancreatic function promoter (acidifier), a single liver function promoter (taurine), or a single intestinal mucosa function promoter (omega 3 oils) improved the

level of fat digestibility (around 5.5 to 6.6%). However, none of these diets increased the level of fat digestibility above 80%, the level considered as normal. When the inventors provided the same old cats with a diet that contains a combination of a pancreatic function promoter (acidifier), a liver function promoter (taurine), and an intestinal mucosa function promoter (omega 3 oils), the improvement in the level of fat digestibility is more dramatic (around 17.5%). Only with this diet did the old cats reach a level of fat digestibility that was considered normal (above 80%). This is a dramatic effect; not even in young healthy cats can fat digestibility be 100%. Moreover, no digestive system is 100% efficient (every meal produces some fecal content).

As supported by the *Declaration*, the results are surprising and unexpected when the percentage of cats that showed an increase in fat digestibility is analyzed as shown in Figure 2 of the *Declaration*. The percent of cats that had an improved fat digestibility when administered the promoters in combination was 90%, as compared to the 67% to 75% for the promoters alone. About 20% more cats will have increased fat digestibility if administered a combination of promoters than if administered one of the promoters alone. Thus, one critical discovery is that the number of cats that benefit from a combination of a pancreatic function promoter (acidifier), a liver function promoter (taurine), and an intestinal mucosa function promoter (omega 3 oils) is much greater than the number of cats that benefit from a single promoter. Figure 2 shows that 90% of the cats improved their fat digestibility, versus only 75% when fed a diet with a single pancreatic function promoter (acidifier), 67 % with a single liver function promoter (Taurine), or 67% with a single intestinal mucosa function promoter (omega 3 oils).

As supported by the *Declaration*, the decrease in fat digestibility in old cats is a complex problem that involves a decrease in pancreatic function, liver function, and/or intestinal mucosal function. In most cases, as is frequent with old age, there is not a clear and consistent malfunction, but a concomitant and interrupted decrease of multiple organ efficiency or malfunction. The inventors made a critical discovery in that the number of cats that benefit from an edible composition including a combination of a pancreatic function promoter (acidifier), a liver function promoter (taurine), and an intestinal mucosa function promoter (omega 3 oils) is much greater than the number of cats that benefit from a single promoter. The beneficial effects of the edible composition lead to an increase in fat digestibility in the cat that also correlates to an increase in the absorption capacity of Vitamin E by the cat.

As such, Appellants submit that the benefits achieved with respect to fat digestibility are clearly illustrated in the *Declaration*. Further, in contrast to the Examiner's statement that "[t]he graph only shows percent of fat digestibility and percent of cats showing improvement, [but] no comparative data for individual cat[s] is shown in terms of lipid absorption," Appellants respectfully submit that the skilled artisan would immediately recognize the relationship between lipid absorption and fat digestibility. Indeed, the present specification is replete with discussions of how increasing vitamin E absorption improves lipid digestibility. As such, Appellants respectfully submit that the *Declaration* provides sufficient evidence of surprising results, and is commensurate in scope with the present claims.

For the reasons discussed above, Appellants respectfully submit that Claims 35, 37, 39-41, 43, 45, 48-52 and 54-68 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Appellants respectfully request that the rejection of Claims 35, 37, 39-41, 43, 45, 48-52 and 54-68 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

III. THE ALTERNATIVE REJECTION OF CLAIMS 35, 45, 48-52 AND 57-64 UNDER 35 U.S.C. §103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS AND, EVEN IF THE EXAMINER ESTABLISHED A *PRIMA FACIE* CASE OF OBVIOUSNESS, APPELLANTS HAVE REBUTTED THE *PRIMA FACIE* CASE OF OBVIOUSNESS

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1. The Examiner Has Failed to Establish a *Prima Facie* Case of Obviousness

In the Examiner's Answer, the Examiner does not dispute the fact that none of the cited references disclose or suggest the presently claimed amounts of taurine. However, the Examiner maintains that the combination of *Fuchs*, *Simpson*, *Watson*, *DeMichele*, and *Margolin* renders

the claimed subject matter obvious. See, Examiner's Answer, pages 19-22. The Examiner states that since the specification teaches vitamins as a liver function promoter, and since *Fuchs* teaches vitamins in 5% amount, one of ordinary skill would have envisaged utilizing another liver function promoter with an expectation to obtain similar results. See, Examiner's Answer, page 21. Appellants respectfully disagree.

Fuchs teaches use of emulsifiers and taurine, but without any usage levels. *Pearson* is said to disclose that taurine can be used to enhance absorption of a drug. *Watson* and *DeMichele* fail to teach the use of or even mention any taurine. The Examiner relies on *DeMichele* for a disclosure of fish oil and *Simpson* and *Margolin* to arguably teach lipid assimilation. Nevertheless, taurine is not disclosed in any of the cited references as a liver function promoter. Instead, the Examiner appears to be using the specification as a guide map for finding the present claims obvious. Indeed, the Examiner even states that "vitamins [are] taught in [the] instant specification as [a] liver function promoter." See, Examiner's Answer, page 21, lines 7-8. From this, the Examiner concludes that since vitamins and taurine are disclosed in the present specification as liver function promoters, and even though none of the cited references discloses taurine as a liver function promoter, the skilled artisan would have known to use taurine as a liver function promoter. As such, the Examiner appears to be using information from the specification to build a case of obviousness against the present claims. This type of hindsight recreation of the pending claims has been found time and again to be improper by the Federal Circuit.

Further, Appellants respectfully submit that even if the prior art discloses vitamins in the amounts presently claimed, there exists no reason why the skilled artisan would have assumed that an amino acid (e.g., taurine) would function similar to the vitamins disclosed by *Fuchs* for the purposes of promoting liver function.

As such, Appellants respectfully submit that the Examiner continues to pick and choose selected portions of the cited references to arrive at the present claims. In fact, what the Patent Office has done here is to apply hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Appellants respectfully submit that if it is proper for the Patent Office to combine any number of references to arrive at the present claims simply because each reference suggests an element of the present claims, then every invention would effectively be rendered obvious. Instead, the

skilled artisan must have a reason to combine the cited references to arrive at the present claims. Appellants respectfully submit that such a reason is not present in the instant case.

2. Appellants Have Rebutted Any *Prima Facie* Case of Obviousness

In the Examiner's Answer, the Examiner also states that Appellants have failed to demonstrate unexpected results for the same reasons discussed above with respect to the first rejection of Claims 35, 45, 48-52 and 57-64. See, Examiner's Answer, pages 22-23. Appellants respectfully disagree with the Examiner's assertions for at least the reasons set forth above.

Accordingly, Appellants respectfully request that the second obviousness rejection of Claims 35, 37, 39-41, 43, 45, 48-52 and 54-68 under 35 U.S.C. §103 be reconsidered and withdrawn.

IV. CONCLUSION

For the foregoing reasons, Appellants respectfully submit that the Examiner's Answer does not remedy the deficiencies noted in Appellants' Appeal Brief with respect to the final Office Action. Therefore, Appellants respectfully request that the Board of Appeals reverse the obviousness rejections with respect to Claims 35, 45, 48-52 and 57-64.

No fee is due in connection with this Reply Brief. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00509 on the account statement.

Respectfully submitted,

K&L GATES LLP

BY 

Robert M. Barrett
Reg. No. 30,142
Customer No. 29157
Phone No. 312-807-4204

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